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1654/14



Docket No. 58069(47126)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: G. Cevc Confirmation No.: 7718

U.S.S.N.: 09/887,493 Group No.: 1654

FILED: June 22, 2001 Examiner: S. D. Coe

FOR: IMPROVED FORMULATION FOR TOPICAL NON-INVASIVE
APPLICATION IN VIVO

Mail Stop: Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 02209-9169

CERTIFICATE OF EXPRESS MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as Express Mail, Label No. EV 437 825 126 US addressed to the: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Date: July 30, 2004

By: 

Judy Daley

Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with the provisions of 37 C.F.R. §§1.56 and 1.97, Applicants herewith submit the publications and/or patents shown on the attached form PTO-1449, for consideration by the Examiner in connection with the examination of the above-identified patent application.

REMARKS

In accordance with the provisions of 37 C.F.R. §1.97, this statement is being filed:

- _____ (1) within three (3) months of the Filing Date or **before the mailing date of the First Office Action** on the merits; or
- _____ (2) within three months of the mailing date of the Search Report issued by the **PCT Patent Office**; or

- _____ (3) after the period defined in (1) but before the mailing date of a **Final Rejection** or **Notice of Allowance**, and the requisite Certification or fee under Rule 1.17(p), namely **\$180.00**, is included herein; or
- X (4) after the mailing date of a **Final Rejection** or **Notice of Allowance** but before the payment of the **Issue Fee**, and the requisite Certification, petition, and petition fee are included herein.

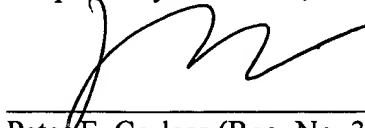
It is respectfully requested that each of the documents shown on the attached form(s) PTO-1449 be made of record in this application. Copies of these documents (CHECK ONE):

- X are enclosed herewith; or
- _____ have been cited in the parent application, and are thus not being resubmitted herein.

FEE AUTHORIZATION

Enclosed herewith is a check in the amount of \$180.00 for submission of these cited references. Should any additional fees associated with the submission be required, the Commissioner is authorized to charge the missing fee to our Deposit Account, No. 04-1105. Any overpayments should be credited to said Deposit Account.

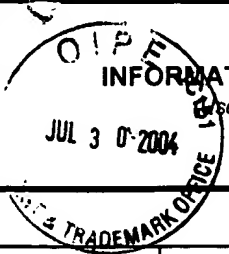
Respectfully submitted,



Date: July 30, 2004

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 <p>INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)</p>				ATTY DOCKET NO. 58069 (47126)		SERIAL NO. 09/887,493		
				Applicant(s): G. CEVC				
				FILING June 22, 2001		GROUP 1654		
U.S. PATENT DOCUMENTS								
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE	
	AA	5,607,692	04/04/1997	Ribier et al.	424	450		
	AB	5,958,379	28/09/1999	Regenold et al.	424	47		
	AC	4,944,948	31/07/1990	Uster et al.	424	450		
	AD	4,911,928	27/03/1990	Wallach	424	450		
	AE	5,238,613	24/08/1993	Anderson	264	22		
	AF	Re. 33,273	24/07/1990	Speaker	210	639		
	AG	4,619,794	28/10/1986	Hauser	264	4.1		
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FOREIGN PATENT DOCUMENTS								
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	BA	07-324029	12.12.1995	JP				
	BB	0 298 280	14.06.1988	EP				
	BC	0 393 707	20.04.1990	EP				
	BD	1 143 656	29.03.1983	CA				
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)								
	CA	G. Cevc et al., Transdermal drug carriers: basic properties, optimization and transfer efficiency in the case of epicutaneously applied peptides, <i>J. Contr. Rel.</i> , 36, pp. 3-16, 1995						
	CB	S. Yuan, et al., Cationic Liposome and Gene Transfer, <i>Progress in Physiological Science</i> , 28(2), pp. 163-165, 1997						
EXAMINER				DATE CONSIDERED				
<p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>								



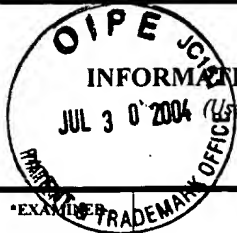
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FORM PTO-1440 INFORMATION DISCLOSURE STATEMENT				DOCKET NO: 58069 (47126)		SERIAL NO.: 09/887,493	
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FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES/NO
	BI	WO 98/17255	30.04.1998	PCT			
	BJ	WO 98/30215	16.07.1998	PCT			
	BK	WO 98/33483	06.08.1998	PCT			
	BL	WO 88/07362	06.10.1988	PCT			
	BM	WO 98/06750	19.02.1998	PCT			
	BN	WO 91/04013	04.04.1991	PCT			
	BO	WO 92/05771	16.04.1992	PCT			
	BP	WO 93/19736	14.10.1993	PCT			
	BQ	WO 93/19737	14.10.1993	PCT			
EXAMINER:					DATE:		



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	BR	WO 90/09782	07.09.1990	PCT			
	BS	WO 87/01938	09.04.1987	PCT			
	BT	3,713,494	29.10.1987	DE			
	BU	3,016,976	13.11.1980	DE			
	BV	1,289,420	24.09.1991	CA			
	BW	2,052,164	26.09.1992	CA			
	BX	1,740,283	28.07.1983	AU			
	BY	0,674,913	04.10.1995	EP			
	BZ	0,704,206	03.04.1996	EP			
	BAA	0,475,160	18.03.1992	EP			
	BBB	0,707,847	24.04.1996	EP			
	BCC	0,280,492	31.08.1988	EP			
	BDD	0,102,324	07.03.1984	EP			
	BEE	0,224,837	24.11.1986	EP			
	BFF	0,211,647	25.02.1987	EP			
EXAMINER:		DATE:					

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<div style="display: flex; justify-content: space-between;"> <div style="width: 15%;"> <p>*EXAMINER INITIAL</p> </div> <div style="width: 85%;"> <p>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</p> </div> </div>					
CC	G. Cevc, Transfersomes, Liposomes and Other Lipid Suspensions on the Skin: Permeation Enhancement, Vesicle Penetration, and Transdermal Drug Delivery, <i>Crit. Rev. Ther. Drug Carrier Syst.</i> , 13(3&4), pp. 257-388, 1996				
CD	A. Klibanov, et al., Activity of amphipathic poly(ethylene glycol) 5000 to prolong the circulation time of liposomes depends on the liposome size and is unfavorable for immunoliposome binding to target, <i>BBA</i> , 1062, pp. 141-148, 1991				
CE	Benner, "The Human Body, The Wonderwork of the Human Body, Structure, Functions, Interactions, Processes and Mechanisms" Weltbild GmbH Augsburg (1995)				
CF	Serva, FEINBIOCHEMICA FUR FORSCHUNG for <i>Serva Feinbiochemica GmbH & Co.</i> (1986/1987)				
CG	Clark, J.M., Jr., "Experimental Biochemistry" Biochemistry Division, Department of Chemistry, University of Illinois, pp. 47-48				
CH	Patel, H.M. "Liposomes as a Controlled-release System" Biomedical Society Transactions 609th Meeting, Leeds, pp. 513-516				
CI	Fieser, L.F., et al. "Organische Chemie" <i>Hans Ruprecht Hensel, 2nd revised edition, Verlag Chemie GmbH, Weinheim/Bergstr</i> (1968)				
CJ	Fluka Chemika-BioChemika Catalogue 16 (1988/89)				
CK	Roeding, J. "Liposomes and Niosomes in Pharmacy and Cosmetic State of the Art Prospects, Techniques of Visualizing Vesicular Systems, Interaction of Liposomes with the Skin" <i>Training Course No. 105 from May 14 to 16, 1990, MARITIM Hotel Nurnberg, Frauentorgraben 11, 8500 Nurenberg</i>				
CL	L. Lobbbecke, et al., "Effects of Short-Chain Alcohols On the Phase Behavior And Interdigitation Of Phosphatidylcholine Bilayer Membranes," <i>Biochimica et Biophysica Acta</i> , 1237, pp. 59-69, 1995				
CM	R. Singh, et al., "Liposomally Encapsulated Diclofenac For Sonophoresis Induced Systemic Delivery," <i>J. Microencapsulation</i> , Vol. 12, No. 2, pp. 149-154, 1995				
CN	T. Henmi, et al., "Application of an Oily Gel Formed by Hydrogenated Soybean Phospholipids as a Percutaneous Absorption-Type Ointment Base," <i>Chem. Pharm. Bull</i> , 42(3), pp. 651-655, 1994				
EXAMINER		DATE CONSIDERED			
<p>*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP Section 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>					

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)					
	CO	M. Foldvari, et al., "Dermal Drug Delivery by Liposome Encapsulation: Clinical and Electron Microscopic Studies," <i>J. Microencapsulation</i> , Vol. 7, No. 4, pp. 479-489, 1990			
	CP	M. Foldari, "In Vitro cutaneous and Percutaneous Delivery and in Vivo Efficacy of Tetracaine from Liposomal and Conventional Vehicles," <i>Pharmaceutical Research</i> , Vol. 11, No. 11, 1994			
	CQ	M. Foldari, "Effect of Vehicle on Topical Liposomal Drug Delivery: Petrolatum Bases," <i>J. Microencapsulation</i> , Vol. 13, No. 5, pp. 589-600, 1996			
	CR	M.E. Planas, et al., "Noninvasive Percutaneous Induction of Topical Analgesia by a New Type of Drug Carrier, and Prolongation of Local Pain Insensitivity by Anesthetic Liposomes," <i>Anesth. Analg.</i> , 75, pp. 615-621, 1992			
	CS	H. Peters, et al., "Pharmacodynamics of a Liposomal Preparation for Local Anaesthesia," <i>Arzneim.-Forsch./Drug Res.</i> , 45(II), Nr. 12, 1995			
	CT	I. Stoye, et al., "Transformation of a Liposomal Dispersion Containing Ibuprofen Lysinate and Phospholipids into Mixed Micelles - Physico-chemical Characterization and Influence on Drug Permeation through Excised Human Stratum Corneum," <i>European Journal of Pharmaceutics and Biopharmaceutics</i> , 46, pp. 191-200, 1998			
	CU	J. Schramlova, et al., "The Effect of an Antiphlogistic Incorporated in Liposomes on Experimentally Induced Inflammation," <i>Folia Biologica (Praha)</i> , 43, pp. 195-199, 1997			
	CV	G. Cevc, "Drug Delivery Across the Skin," <i>Exp. Opin. Invest. Drugs</i> , 6(12), pp. 1887-1937, 1997			
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OTHER DOCUMENTS							
	CW	G. CEVC et al., Transfersomes-mediated transepidermal delivery improves the regio-specificity and biological activity of corticosteroids in vivo, <i>Journal of Controlled Release</i> 45 (1997) 211-226					
	CX	V.M. KNEPP et al., CONTROLLED DRUG RELEASE FROM A NOVEL LIPOSOMAL DELIVERY SYSTEM II. TRANSDERMAL DELIVERY CHARACTERISTICS, <i>Journal of Controlled Release</i> 12 (1990) March, No. 1, Amsterdam, NL, pp. 25-30					
	CY	C.E. Price, "A REVIEW OF THE FACTORS INFLUENCING THE PENETRATION OF PESTICIDES THROUGH PLANT LEAVES" on I.C.I. Ltd., Plant Protection Division, Jealott's Hill Research Station, Bracknell, Berkshire RG12 6EY, U.K., pp. 237-252					
	CZ	K. Karzel and R. K. Liedtke, "MECHANISMEN TRANSKUTANER RESORPTION" on <i>Grandlagen.Basics</i> , pp. 1487-1491					
	CAA	Michael Mezei, "LIPOSOMES AS A SKIN DRUG DELIVERY SYSTEM" 1985 Elsevier Science Publishers B.V. (Biomedical Division), pp. 345-358					
	CBB	Adrienn Gesztes and Michael Mezei,, "TOPICAL ANESTHESIA OF THE SKIN BY LIPOSOME-ENCAPSULATED TETRACAINE" on <i>Anesth Analg</i> , 1988; 67: pp. 1079-81					
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	CGG	Ronald R. Burnette et al., "CHARACTERIZATION OF THE PERMSELECTIVE PROPERTIES OF EXCISED HUMAN SKIN DURING LONTOPHORESIS" on <i>Journal of Pharmaceutical Sciences</i> , Vol. 76, No. 10, October 1987, American Pharmaceutical Association, pp. 765-773					
	CHH	E.C. Katoulis et al., "EFFICACY OF A NEW NEEDLELESS INSULIN DELIVERY SYSTEM MONITORING OF BLOOD GLUCOSE FLUCTUATIONS AND FREE INSULIN LEVELS" on <i>International Journal of Artificial Organs</i> , Vol. 12, No. 5, 1989, pp. 333-338					
	CII	Ovals Siddiqui et al., "NONPARENTAL ADMINISTRATION OF PEPTIDE AND PROTEIN DRUGS" on <i>CRC Critical Reviews in Therapeutic Drug Carrier Systems</i> , Volume 3, Issue 3, pp. 195-208					
	CJJ	Cevc, G. et al., "Ultraflexible vesicles, Transfersomes, have an extremely low pore penetration resistance and transport therapeutic amounts of insulin across the intact mammalian skin," <i>Biochimica et Biophysica Acta</i> , 1368 pp. 201-215 (1998)					
	CKK	Cevc, G., "Material Transport Across Permeability Barriers by Means of Lipid Vesicles," <i>Handbook of Biological Physics</i> , Vol. 1, pp. 465-490 (1995)					
	CLL	Mayer, L.D. et al., "Vesicles of variables sizes produced by a rapid extrusion procedure," <i>Biochimica et Biophysica Acta</i> , 858 pp. 161-165 (1986)					
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OTHER DOCUMENTS							
	COO	Beyer, C. et al., "Micro Emulsions" <i>Pharmazie in unserer Zeit</i> , No. 2 (1983)					
	CPP	Lichtenberg, D. et al., "SOLUBILIZATION OF PHOSPHOLIPIDS BY DETERGENTS STRUCTURAL AND KINETIC ASPECTS," <i>Biochimica et Biophysica Acta</i> , 737 pp. 285-304 (1983)					
	CQQ	Lasch, J. et al., "Interactions of external lipids (lipids vesicles) with the skin," <i>Journal of Liposome Research</i> , 5(3) pp. 543-569 (1995)					
	CRR	Berger, M., "Oral Insulin 1922-1992: The History of Continuous Ambition and Failure," Heinrich-Heine-University, Dusseldorf, Germany					
	CSS	Cevc. G. et al., "The skin: a pathway for systemic treatment with patches and lipid-based agent carriers," <i>Advanced Drug Delivery Reviews</i> 18 pp. 349-378 (1996)					
	CTT	M.L. Jackson, et al. "SOLUBILIZATION OF PHOSPHATIDYLCHOLINE BILAYERS BY OCTYL GLUCOSIDE," <i>biochemistry</i> 1982, 21, 4576-4582					
	CUU	P. Vinson, et al., "VESICLE-MICELLE TRANSITION OF PHOSPHATIDYLCHOLINE AND OCTYL GLUCOSIDE ELUCIDATED BY CRYO-TRANSMISSION ELE TRON MICROSCOPY," <i>Biophys. J., Biophysical Society</i> Volume 56 October 1989 669-681					
	CVV	K. Edwards, et al., "EFFECTS OF TRITON X-100 ON SONICATED LECITHIN VESICLES," <i>Langmuir</i> , Vol. 5, No. 2, 1989 pp. 473-478					
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